

REMARKS

We note that claims 1, 3-8, and 10-11 stand allowed. (Paper No. 02142004 at 9.)

Claims 22 and 29 have been amended to recite "consisting of...." Support for these amendments is found in the specification at, for example, page 1, lines 16-22 and page 2, lines 1-4; and in Examples 1 and 3.

Claims 23 and 30 have been amended to recite "further consisting of ..." to conform with the claims from which they depend. Support for these amendments is found in the specification at, for example, page 1, lines 9-11 and 16-22; page 2, lines 1-4; page 3, lines 13-19, and in Examples 1 and 3.

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments are respectfully solicited.

Rejection under 35 USC § 102

Claims 22-24 and 26-34 were rejected solely under 35 USC § 102(b) as anticipated by Schmidt et al., U.S. Patent No. 4,605,666 ("Schmidt"). (Paper No. 02142004 at 2.)

For the reasons set forth below, the rejection respectfully is traversed.

Schmidt discloses a powder containing a water-soluble vitamin prepared by spray drying an aqueous slurry of the vitamin, a binder, a lubricant, and optionally an adsorbent and an additional excipient. (Col. 1, line 52 - col. 2, line 54).

In making the rejection, the Examiner asserted only that "[t]his rejection is analogous to the rejection mailed 8/26/2003." (*Id.*)

In the August 2003 Office Action the Examiner asserted that Schmidt discloses "a powder or tablet composition, comprising a water-soluble vitamin (i.e., sodium ascorbate, ascorbic acid); a binder (i.e., microcrystalline cellulose); a lubricant (i.e., stearic acid, magnesium stearate, calcium stearate) and an excipient (i.e., pectin, starch), wherein the final powder formed will contain at least 80% (preferably at least 90) percent by weight of the water soluble vitamin, less than 15 (preferably less than 9) percent by weight of binder ... 0.2 to 5 percent by weight of the lubricant and less than 3 percent of other excipients." (Paper No. 16 at 3.) The Examiner then summarily concluded that "[o]ne of ordinary skill in the art is able to 'at once envisage' the claimed composition within the sufficiently limited or well-delineated components and their dosage ranges, the composition is anticipated." (*Id.*)

The Examiner, however, acknowledged that "Schmidt is silent about the functional characteristic of using pectin as a binder..." (*Id.*) To fill this acknowledged gap, the Examiner asserted that "the functional characteristic of using pectin as a binder ... must be inherent to the pectin. Therefore, the claimed composition is still properly rejected by a reference, even if the reference does not address or acknowledge the property." (*Id.*)

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984). And, the Examiner must show that there is no

difference between what is claimed and what is disclosed in the applied reference. *In re Kalm*, 154 USPQ 10, 12 (CCPA 1967); *Scripps v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991).

Initially we note, the rejection is factually deficient. The rejection fails to identify where Schmidt discloses a "composition having a compressibility superior to a composition comprising L-ascorbic acid and/or a pharmaceutically acceptable salt thereof and about 0.1 to about 10% by weight of a standard binder," as claimed. In fact the Examiner acknowledged this shortcoming, Schmidt "is silent about the functional characteristic of using pectin as a binder...." The Examiner, however, seeks refuge in the "inherent" properties or characteristics of pectin. (Paper No. 16 at 4.)

The "inherent" properties of pectin are irrelevant in a determination of anticipation of the ***claimed composition***. It is this composition for which the Examiner must demonstrate "identity of invention" with the disclosure of Schmidt. Simply stated, pectin is not what is claimed. The superior compressibility of the claimed composition is what is recited and the rejection is silent concerning the compressibility of the claimed composition. The Examiner's argument is analogous to arguing that flour is "inherently" white and, therefore, a chocolate cake containing flour must also be white. The Examiner's position is both factually and logically incorrect. For this reason alone, the rejection is deficient and must be withdrawn.

None of the exemplified embodiments of Schmidt discloses the use of pectin as a binder. (Col 3, line 27 - col. 6, line 53; Examples 1-5 and comparison example.) None of the exemplified embodiments of Schmidt discloses the use of pectin even as an excipient. (*Id.*) In fact, pectin is disclosed simply as one of twelve identified

carbohydrates, all of which are non-preferred excipients that may be present in an amount "less than three percent." (See Col. 2, lines 45-66.) According to Schmidt, the presence of such a carbohydrate in a composition does not lead to superior compressibility in that composition, "inherently" or otherwise:

U.S. Pat. No. 3,293,132 describes a continuous process for making a vitamin C powder by spray drying. The process involves spray drying from 75 to 95 parts by weight of ascorbic acid, **from 5 to 25 parts by weight of a carbohydrate**, and from 0.5 to 5 parts by weight of a film-producing hydrophilic, organic colloid material such as gelatin, water-soluble derivatives of casein, water-soluble gums, and water-soluble derivatives of cellulose. Although the process is continuous, a lubricant is not one of the spray dried components. Instead, the lubricant is blended into the spray-dried powder after spray drying. Consequently, **the powder taken directly from the spray dryer cannot be directly compressed into tablets**. Moreover, the powder disclosed in this patent is likely to discolor at use conditions. (Col. 1, lines 20-34.)

Acknowledging the deficiency in compressibility of powders containing a carbohydrate, e.g., pectin, Schmidt discloses that its claimed process:

is unique because the lubricant is mixed with all of the other components during the spray-drying.... powders prepared by this process ... are directly compressible into tablets without needing the addition of other excipients, and are unique because they do not demix. They are also color stable tablets which have acceptable disintegration times and hardness. (Col. 1, lines 41-49.)

Thus, according to Schmidt, the presence of a "carbohydrate," such as pectin, in a composition does not "inherently" lead to superior compressibility of that composition. In fact, according to Schmidt, such compositions have inferior compressibility and cannot be directly compressed into tablets.

Thus, the document relied on by the Examiner in rejecting the claims actually contradicts his assertion that "such property or characteristic must be inherent to the pectin." The only carbohydrate containing powders discussed in Schmidt have inferior compressibility, a problem which Schmidt purports to solve with its method.

All that remains is the Examiner's unsupported supposition that the "functional characteristic must be inherent to the pectin." Such unsupported conjecture is not sufficient to support a rejection under 102:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. ***Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.***'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

* * *

In relying upon the theory of inherency, the ***examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.***" *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). (MPEP § 2112, 8th Ed. Rev. 1, Feb. 2003, p. 2100-52.) (Emphasis added.)

The present rejection offers none of the requisite evidence or technical reasoning to support the Examiner's contention that the "functional characteristic must

be inherent to the pectin.” Thus, the Examiner has not demonstrated that Schmidt discloses (inherently or otherwise) a “composition having a compressibility superior to a composition comprising L-ascorbic acid and/or a pharmaceutically acceptable salt thereof and about 0.1 to about 10% by weight of a standard binder.” That, however, is what is claimed. Accordingly, the rejection fails to disclose where in Schmidt each and every element of claims 22-24 and 26-34 are suggested, let alone disclosed. The rejection, therefore, fails to set forth a *prima facie* case of anticipation. Moreover, the rejection is also insufficient to support a *prima facie* case of obviousness. For these additional reasons, the rejection is factually deficient and must be withdrawn.¹

In responding to our Previous Response, dated November 26, 2003, the Examiner stated that his “view had been changed during the prosecution of the instant application, however, this is not [the] same as the allegedly ‘unambiguous admission that there are at least four differences between claims 22-24 and 26-34 and Schmidt.’” (Paper No. 02142004 at 5.) While Examiner’s position may have changed, such retreat by the Examiner cannot erase his previous statements from the record.

In the Office Action dated February 5, 2003, the Examiner rejected claims 1-13 and 22-34 solely under 35 U.S.C. 103(a) over Schmidt and if necessary, further view of Newlin, U.S. Patent No. 3,615,591 (“Newlin”), Chiralt et al., 1999 IFT Annual Meeting (“Chiralt”), and Hussaini et al., A Guide to Halal food Selection 1993 (“Hussaini”). (Paper No. 11 at 3.) The Examiner stated only that “[t]his rejection is analogous to the original rejection” found in the Office Action dated June 26, 2002. (*Id.* citing Paper No. 9.)

¹ Should the Examiner persist in making the rejection on the stated grounds, he is requested to provide

In Paper No. 9, the Examiner could not have been more clear in acknowledging that:

Schmidt differs from the claimed invention in 1) the specific amounts of pectin in the composition, about 0.1 to about 10%, more specifically about 0.5 to 5%, based on the total weight of the composition; 2) 95-99% by weight of L-ascorbic acid and/or a pharmaceutically acceptable salt; 3) the use of citrus pectin; and 4) the functional characteristic of pectin as a binder. (Paper No. 9 at 4; See also, Paper No. 3 at 4.)

Thus, the record does indeed reflect an unambiguous admission that there are at least four differences between claims 22-24 and 26-34 and Schmidt. And, the Examiner's decision to re-characterize the Schmidt document does not change this unambiguous admission of gaps in Schmidt, nor does it render the "argument irrelevant to the merits of the case." The Examiner's express admission that Schmidt fails to disclose each and every element of the claimed invention in at least four distinct ways is an ***unambiguous admission that Schmidt does not anticipate claims 22-24 and 26-34***. Notwithstanding the Examiner's flip-flop as to just what Schmidt discloses, such an admission goes to the very heart of the "merits of the case."

As we previously noted, this § 102 rejection is nothing more than a belated attempt to rewrite the history of this prosecution, which spans three and one-half years. This rejection is contrary to the PTO's stated policies and is a textbook example of the kind of piecemeal prosecution frowned upon by the PTO. "Piecemeal examination should be avoided as much as possible. The examiner ordinarily should reject each claim on all valid grounds available, avoiding, however, undue multiplication of references." MPEP 707.07(g) (8th Ed., Rev. 1, February 2003, p. 700-116.) If the

the ***evidence or reasoning*** required to support his assertion of inherency.

PTO desired to assert a § 102 rejection of claims 22-24 and 26-34 based on Schmidt, the time to have done so was in Paper No. 11 – the Office Action following the September 27, 2002 Response presenting claims 22-24 and 26-34.

At the very least it is incumbent on the Examiner to fully explain his change of heart on the record so that the file wrapper of this application is complete and so that the Applicant may present arguments to rebut the Examiner's new characterization of Schmidt. Absent such explanation, the Examiner's own admission that Schmidt fails to anticipate the claimed invention stands unrebutted and for this reason also, the rejection must be withdrawn.

Notwithstanding the forgoing and only to expedite prosecution, claims 22 and 29 have been amended to recite "consisting of...." Accordingly, the rejection has been rendered moot and should be withdrawn.

Rejection under 35 USC § 103

Claim 25 was rejected solely under 35 USC § 103(a) as being unpatentable over Schmidt in view of Hill, U.S. Patent No. 3,946,110 ("Hill"). (Paper No. 16 at 5.)

For the reasons set forth below the rejection, respectfully is traversed.

Schmidt is summarized above.

Hill discloses "improvements in analgesic and antifebrile or antipyretic compositions ... by compounding them with natural, water-swelling gums, preferably those having a poly-uronic acid molecular structure such as pectins and alginates of various origins, tragacanth, karaya, and other gums such as carrageenin." (Col. 1, line

11 - col. 2, line 1.) Hill discloses the use of citrus pectins at, for example, column 4, lines 46-50 and Example 1, column 8, line 43.

In making the rejection, the Examiner asserted only that "[t]his rejection is analogous to the rejection mailed 8/26/2003." (Paper No. 02142004 at 3.)

In the Previous Rejection, the Examiner relied solely on the characterization of Schmidt found in the § 102 rejection. (Paper No. 16 at 5.) The Examiner acknowledged, however, that Schmidt differs from the presently claimed invention "in the use of citrus pectin in said composition." (*Id.*) To remedy this acknowledged gap, the Examiner relied upon Hill as disclosing "the use of pectin, namely citrus pectin, in preparing medicinal tablet composition (Examples 9-16)." (*Id.*) The Examiner also asserted that Hill discloses "that pectins are commonly found in edible fruits and vegetables, including apples and citrus fruits, and are generally isolated from them." (*Id.*) The Examiner then concluded that "[t]o incorporate such teaching into the teaching of Schmidt, would have been obvious in view of Hill" (*Id.*)

To further bolster the rejection the Examiner asserted that "[o]ne having ordinary skill in the art would have expected in view of Hill that citrus pectin would be preferred in preparing pharmaceutical tablet composition, maybe due to its lighter color than other source of pectins. Furthermore, one ... would have been motivated to modify [Schmidt] with the reasonable expectation of success, such that said composition can be readily formed into tablet when it is compressed." (*Id.*)

As is well settled, the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785,

788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

As we noted in our Previous Response, the rejection uses the wrong standard for determining obviousness. The Examiner relies upon three different standards in making the rejection:

- 1) "[t]o incorporate such teaching ... would have been obvious;
- 2) [o]ne ... would have expected ... that citrus pectin would be preferred;

and

- 3) one ... would have been motivated to modify

Accordingly, the rejection fails to provide any reason why one would be motivated, let alone impelled, to combine Schmidt and Hill in the manner to arrive at the claimed composition. Thus, the rejection fails to set forth the facts and reasoning required to support a *prima facie* case of obviousness.

In the present Office Action the Examiner responded to this argument by asserting that "the applicants' alleged 'the wrong standard for determining obviousness' or 'none of these standards is found in the statute or precedential authority' is irrelevant to the merits of the case." (Paper No. 02142004 at 7.) Contrary to the Examiner's assertion, the application of the correct standard is essential to making a proper determination of *prima facie* obviousness²:

The legal concept of *prima facie* obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process. See *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143

² We note that Examiner compounds his error by again reciting the improper "motivated to modify..." standard in the present Office Action. (See Paper No. 02142004 at 8.)

(CCPA 1976); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); *In re Saunders*, 444 F.2d 599, 170 USPQ 213 (CCPA 1971); *In re Tiffin*, 443 F.2d 394, 170 USPQ 88 (CCPA 1971), *amended*, 448 F.2d 791, 171 USPQ 294 (CCPA 1971); *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). The ***examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness.*** If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness.

* * *

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, ***the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person.*** (MPEP § 2141, p. 2100-123.)

However, the Examiner applied three different standards; none of which is the proper standard. And the Examiner's knee-jerk gainsaying of the Applicants' argument does not render it "irrelevant to the merits of the case." On the contrary, this argument bears directly on the merits of the case. Because the Examiner used the wrong standard(s), it is both legally and factually impossible for the rejection to present a "proper determination" of a *prima facie* case for obviousness. Because the rejection does not present a *prima facie* case of obviousness it must be withdrawn.

As set forth above, a rejection based on Schmidt alone is insufficient under § 102 and § 103. The Examiner has already admitted on the record that Schmidt has at least four factual gaps that prevent it from being cited alone under § 102 or § 103. (See Paper No. 9 at 4.) The Examiner previously sought to fill these gaps with Newlin, Chiralt, and/or Hussaini. (Paper No. 11 at 4.) That rejection, however, was

withdrawn in the Previous Office Action. The withdrawal of the rejection was an admission that Newlin, Chiralt, and Hussaini, even in combination, were insufficient to fill the gaps in Schmidt and render the claims unpatentable.

Having expressly conceded the deficiencies in Schmidt, the Examiner must provide evidence of: 1) a suggestion or motivation to combine the cited documents found in the documents themselves or in the knowledge generally available in the art; and 2) that when properly combined the cited documents disclose or suggest each and every element of the claimed invention. (See MPEP 2143, pp. 2100-124 to 2100-125.) This the Examiner has not done.

Hill is cited by the Examiner only as disclosing citrus pectin. Accordingly, even if the Examiner's combination of Schmidt and Hill is accepted as proper, *arguendo*, the combination fails to account for the fact that:

Schmidt differs from the claimed invention in 1) the specific amounts of pectin in the composition, about 0.1 to about 10%, more specifically about 0.5 to 5%, based on the total weight of the composition; 2) 95-99% by weight of L-ascorbic acid and/or a pharmaceutically acceptable salt; ... and 4) the functional characteristic of pectin as a binder. (Paper No. 9 at 4; See *also*, Paper No. 3 at 4.)

Even in combination, Schmidt and Hill leave at least three of the gaps acknowledged by the Examiner unfilled. Accordingly, the rejection is factually insufficient and should be withdrawn.

In response, the Examiner again simply ignored the Applicants' argument. "Applicant's discussion of the references cited in Paper No. 9 and 11 (namely Newlin, Chiralt, and/or Hussaini) and 'at least four factual gaps that prevent it from being cited under 102 or 103' are irrelevant to the merit of the case." (Paper No. 02142004 at 7.)

However, the record does contain an unambiguous admission by the Examiner that there are at least four differences between claim 25 and Schmidt. The Examiner's re-characterization of Schmidt does not change his unambiguous admission of these gaps. And, contrary to the Examiner's assertion, his characterization of the primary reference used in rejecting the claim goes to the very heart of the rejection.

At the very least it is incumbent on the Examiner to fully explain how these factual gaps in Schmidt have mysteriously disappeared when there has been no change in the claim or in Schmidt. Absent such explanation, the Examiner's unambiguous admission that Schmidt differs from the claimed invention in at least four ways stands un rebutted. And, even accepting the Examiner's characterization, Hill at best, fills only one of these gaps. Accordingly, based on the Examiner's statements the current rejection leaves three acknowledged factual gaps in Schmidt unfilled. For this reason, the rejection is insufficient and must be withdrawn.

Notwithstanding the forgoing and only to expedite prosecution, claim 22 from which claim 25 depends, has been amended to recite "consisting of...." Accordingly, the rejection has been rendered moot and should be withdrawn.

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Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on June 7, 2004.


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